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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,259	10/28/2003	Jeffrey Browning	A041 CON	7052

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/696,259	BROWNING, JEFFREY	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed 10/28/2003 is acknowledged and has been entered. Claims 1-20 are pending in the application and are addressed herein.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to a nucleotide, a vector and a host cell classified in class 536, subclass 23.1, and class 435, subclass 69.1 and 320.1 for example.

II. Claims 8-11, drawn to a polypeptide, classified in class 530, subclass 350+, for example.

III. Claim 12 and 13, drawn to a hybridoma and an antibody, classified in class 530, subclass 387.1+, for example.

IV. Claims 14-17, drawn to a method of modulating the immune system of a subject, classified in class 530, subclass 350+, for example.

V. Claim 18, drawn to a method of decreasing signal transduction in a cell, classified in class 530, subclass 350+, for example.

VI. Claim 19, drawn to a method of targeting a molecule to a cell, classified in class 530, subclass 350+, for example.

VII. Claim 20, drawn to a method of gene therapy, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are unrelated products. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, invention I is drawn to nucleic acid, a vector comprising the nucleic acid, a cell containing the vector, and a process for making a polypeptide using the cell, while Invention II is drawn to a protein and Invention III is drawn to a hybridoma cell and antibody. Nucleic acids, polypeptides and antibodies (as well as hybridoma cells which produce antibodies) are structurally and functionally distinct products. For instance, nucleic acid sequences are comprised of nucleotides and can be useful for making a polypeptide sequence encoded by the nucleic acid sequence or they can be used in hybridization assays such as Northern blot assays. Proteins are comprised of amino acids and can have various different functions in a cell including enzymatic functions or structural functions. Antibodies are specific types of proteins comprised of amino acids sequences and function in the immune response of a subject and can be used for specifically binding to a target molecule for purification or identification purposes; furthermore, hybridomas are specific types of fused cells which are useful for producing specific monoclonal antibodies. Therefore the Inventions of Groups I-III are unrelated patentably distinct inventions.

Inventions IV-VII are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention IV is a method of modulating the immune system of a subject, invention V is a method of inhibiting signal transduction in a cell, invention VI is a method of targeting molecules to a

cell, and invention VII is a method of gene therapy. These inventions involve different method steps with different desired results (i.e., different effects). For instance, Inventions IV-VI require the use of a polypeptide while Invention VII requires the use of a nucleic acid sequence. Furthermore, Invention IV has the desired effect of modulating an immune response in a subject, Invention V has the desired effect of inhibiting signal transduction in a cell, and Invention VI has the desired effect of targeting molecules to cells. Therefore the inventions of Groups IV-VII are unrelated patentably distinct inventions.

Invention I is unrelated to inventions IV-VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, invention I is a nucleic acids sequence which is not used in the methods of Inventions IV-VI. Therefore, Invention I is unrelated to Inventions IV-VI.

Inventions III is unrelated to inventions IV-VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, invention III is an antibody and a hybridoma cell which produces the antibody. Te antibody and hybridoma cell of Invention I is not used in the methods of Inventions IV-VII. Therefore, Inventions III is unrelated to Inventions IV-VI.

Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the product, (i.e., the nucleic acid sequence of Invention I) can be used in a materially different process of using the product. For instance, the nucleic acid sequence can be used for producing the polypeptide it encodes in a cell in vitro or in a cell-free system. Alternatively the nucleic acid can be used to make probes which can be used in hybridization assays such as Northern blot Assays, Southern blot Assays, or in PCR amplification reactions or the nucleic acid itself can be used as a probe in hybridization assays. Therefore, Inventions I and IV-VI are patentably distinct Inventions.

Invention II is related to each of Inventions IV-VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (i.e., the polypeptide of Invention I) can be used in a materially different process of use. For instance, the polypeptide can be used to making polyclonal antibodies which specifically hybridize to the polypeptide.

Because these inventions are distinct for the reasons given above and the search required for each invention is different, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention.

The species of DNA molecules are as follows:

1) A DNA molecule which encodes SEQ ID NO: 4
2) A DNA molecule which encodes SEQ ID NO: 5
3) A DNA molecule which encodes SEQ ID NO: 6

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of DNA molecule as indicated above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-7 and 20 are generic to the indicated species of DNA molecules.

The species of polypeptide molecules are as follows:

1) A polypeptide comprising SEQ ID NO: 4
2) A polypeptide comprising SEQ ID NO: 5
3) A polypeptide comprising SEQ ID NO: 6

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of polypeptide molecule as indicated above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 8-11 and 14-19 are generic to the indicated species of polypeptide molecules.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

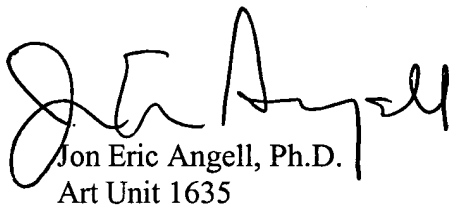
A telephone call was made to Margaret Pierri on 10/22/2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jon Eric Angell, Ph.D.
Art Unit 1635